IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	**Master File No. 2:12-MD-02327** **MDL 2327** **JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**
THIS DOCUMENT RELATES TO ALL PLAINTIFFS LISTED IN EXHIBIT "A" TO THE INITIAL MOTION	

PLAINTIFFS' REPLY IN SUPPORT OF THEIR MOTION TO EXCLUDE THE GENERAL CAUSATION OPINIONS OF DEFENSE EXPERT MICHEAL P. WOODS, M.D.

In defending proffered expert Michael P. Woods, M.D., Defendants have largely relied on prior orders by this Court in which a particular witness with a similar infirmity has been permitted to testify. While there is nothing unreasonable about relying on the Court's prior orders, the approach misses the central point of Plaintiffs' motion to exclude Dr. Woods. A comprehensive review of his qualifications and knowledge falls short of most other experts on both sides of this litigation and, more importantly, falls short of what *Daubert* requires.

To use an illustrative example, in countering Plaintiffs' argument that Dr. Woods has no relevant design experience, Defendants assert that his experience as a surgeon constitutes relevant design experience, citing this Court's opinion in *Tyree v. Boston Scientific Corp.*, 54 F. Supp. 3d 501, 550 (S.D. W. Va. 2014), *as amended* (Oct. 29, 2014). This Court's full statement was that the physician in question, Dr. Ostergard, was qualified based on all of the following: "He has performed countless pelvic reconstruction surgeries, instructed others on the performance of these surgeries, participated in the development of pelvic mesh devices, and

authored several peer-reviewed articles on the safety and efficacy of polypropylene mesh products." *Id.*

Here, Dr. Woods only meets half of those criteria. He is a surgeon, and he testified that he has taught others to implant TVT devices. (*See* Def. Resp. at 8). However, his product design experience is limited to providing "input" and consulting, (*id.* at 8-9)—which was very limited, as discussed below—and there is no indication in his report or in the Defendants' response that he has authored peer-reviewed articles about mesh products.[1]

Those facts alone do not disqualify Dr. Woods, but the point is that no two experts have the same basket of credentials, and this Court has consistently analyzed an expert's entire profile in determining whether the expert is qualified, and whether his methodology was reliable. No expert with a similar set of credentials and deposition testimony to Dr. Woods has been permitted to testify. Dr. Woods has experience as a surgeon, and he conducted a literature review. While that is a useful start, he lacks additional credentials and, more importantly, his deposition demonstrated a lack of knowledge in several key areas related to product design. In addition, Defendants' efforts to limit his warnings opinions cannot change the fact that he admitted a lack of expertise in that area, or that his opinions are entirely unsupported.

For these reasons, the Court should exclude Dr. Woods from testifying in the Ethicon Wave 1 cases.

[1] *See generally* Woods Report, Ex. C to Pl. Mot., *see also generally* Def. Resp.

ARGUMENT

I. Dr. Woods's deposition answers show that he is not qualified by knowledge to opine on design issues, despite his literature review; and his failure to consider any Ethicon documents demonstrates the lack of a reliable methodology in reaching his opinions about safety and design.

Dr. Woods lacks the qualifications to opine about product design, and his methodology in arriving at his opinions was inadequate under *Daubert*. The Rule 702 factors as it relates to qualifications are "knowledge, skill, experience, training, or education." Fed. R. Evid. 702. Defendants assert that his opinions are based on his education, medical training, clinical experience, and "extensive review" of medical literature and other documents. (Def. Resp. at 2). However, Defendants have not identified anything about Dr. Woods's education or training that taught him about the issue of product design, specifically.

As for his clinical experience, Defendants claim that he has taught other surgeons the procedure; that he has worked with engineers, offering "input"; and that he has been a consultant on medical devices that have been patented. (*Id.* at 8-9). Teaching other surgeons to implant the device does not make him an expert on product design. While consulting work on design could, in theory, support expertise in that area, Dr. Woods's testimony on cross-examination revealed the limitations of his consulting work.

> Q. Do you know what a company research is before a product is designed or released?
>
> A. I have vague ideas, but I -- I have no solid regulatory aspect at all.
>
> Q. Okay.
>
> A. I'm usually asked, you know, such as with my work with Ethicon is, "What is your opinion on this?" I worked on a couple of the other – the other, like with TVT Secur, and then looking at some of the evolution ones, but as in the regulation, that is something that's not what I would – I've got other things to be worried about.

> Q. You wouldn't consider yourself an expert in that area?
>
> ***
>
> THE WITNESS: I feel that I do not have the knowledge base. I may have a very vague knowledge base but not the level that would be required in manufacturing.[2]

Defendants' remaining arguments go to whether Dr. Woods is qualified by knowledge, based on his review of the literature and other documents. Plaintiffs are not asserting that one could not be qualified by knowledge based on a literature review. But Dr. Woods's TVT deposition revealed that **this witness** is not sufficiently knowledgeable to qualify as an expert on that basis, in the area of product design. His testimony, as discussed in Plaintiffs' initial memorandum, speaks for itself and does not need to be repeated here. But despite having given "input" on design projects, Dr. Woods did not even know such basic information as the purpose of a design failure modes and effects analysis ("dFMEA").[3]

For these reasons, Dr. Woods should be excluded from giving design opinions, due to lack of qualifications.

In addition, Dr. Woods did not engage in a reliable methodology. Defendants claim that he reviewed internal Ethicon documents related to the TVT device, (Def. Resp. at 3 n.2), but Dr. Woods's testimony contradicts that assertion. Immediately after the passage cited by Defendants he clarified that he was "aware of the internal documents." He then boasted that he "absolutely" did not rely on any internal documents in forming his opinions.[4] Without having reviewed any internal documents regarding the TVT or TVT-O products, Dr. Woods could not have a

[2] Woods TVT Dep., Oct. 5, 2015, portions attached as Exhibit A, at 97:7-98:6 (objections omitted). While the answer touched on regulatory issues and referenced "manufacturing," Dr. Woods was not asked about those areas.
[3] *Id.* at 99:25-100:7.
[4] *Id.* at 15:6-18.

knowledge base as to the design processes, the design history, or the issues identified by Ethicon over the years.

Defendants assert that this Court's order in *Winebarger v. Boston Scientific Corp.*, No. 2:13-CV-28892, 2015 WL 1887222 (S.D. W. Va. Apr. 24, 2015), is distinguishable because the focus of that opinion was on Ethicon's design process. However, the Court's ruling is equally applicable here. This Court noted in *Winebarger* that "[r]eliance on literature and experience is not dispositive … because the court must also ensure that the expert has reliably applied his methodology to the facts of the case, with the same level of intellectual rigor that characterizes the practice of an expert in [that] field." *Id.* at *14 (quotations and citations omitted). The Court concluded that "[w]ithout any reliable, demonstrated knowledge of BSC's internal design procedures, Dr. Shull cannot substantiate his opinion that these procedures were (1) departures from the norm; (2) not followed by BSC; or (3) lacking in any way." *Id.*

Here, the relevant question is whether Defendants' product was negligently and/or defectively designed, however those terms are defined within a given state. Without having relied on any internal documents, and without any knowledge[5] of Ethicon's design processes—or design processes generally, Dr. Woods cannot give a reliable opinion. He cannot know whether the product is reasonably safe, or whether Ethicon was negligent in designing it, without any information about what steps Ethicon took—or failed to take—to ensure the safety of the product. Thus, the Court's reasoning in *Winebarger* is applicable here, even though the circumstances are slightly different.

[5] The word "knowledge" is important. Defendants claim that under Plaintiffs' logic, several of Plaintiffs' experts would not be qualified. (Def. Resp. at 9). However, Plaintiffs have not advocated for a per se rule requiring **experience** with product development to opine about design. The argument is that Dr. Woods's complete lack of **knowledge** about the design development process is a factor favoring his exclusion.

In addition, this Court should reject the assertion that an expert who was excluded on "design" was still allowed to opine about the safety and the efficacy of the product. Such a ruling would be difficult to enforce, as safety and efficacy are inextricably intertwined with the design analysis, under the laws of many states. In reality, this Court allowed Dr. Culligan to opine about safety and efficacy while excluding his opinions on the physical properties of the mesh. *Winebarger*, 2015 WL 1887222, at **33-35.[6]

In addition, the Court should reject Defendants' arguments related to Dr. Woods's personal complication rates. Plaintiffs are not, as Defendants suggest, asking for exclusion of any testimony related to Dr. Woods's clinical experience. Plaintiffs are, however, making these two points:

- Dr. Woods's personal complication (and satisfaction) rates, which he has stated as numerical values, are unreliable without any information to support them; therefore, they should be excluded.
- Dr. Woods's reliance on these highly questionable complication rates in forming his opinions is another basis to question the reliability of his methodology in reaching his ultimate conclusions about the TVT products.

This Court's orders do not contradict those points. For instance, Defendants cited to *Tyree*, in which the Court permitted Dr. Green to opine that has not seen evidence of degradation in his clinical practice. *Tyree*, 54 F. Supp. 3d at 585. The Court did not bless an expert pulling numbers out of thin air and citing them as "personal complication rates" without any basis to verify those numbers.

[6] Dr. Woods admitted that he is not a biomaterials expert. (Woods Dep., Ex. A, at 92:15-18).

This Court, therefore, should conclude that Dr. Woods's methodology was not reliable. He did not rely on important documentation regarding Ethicon's design processes, and he did rely on complication rates that have no basis in fact.

II. Dr. Woods's admission that he lacks warnings expertise was not limited to a regulatory context, and regardless, the opinions he offers have absolutely no support in his expert report.

Dr. Woods should also be excluded from giving warnings opinions. He has admitted his lack of expertise, and his report provides no support for his opinions.

On the first issue, Defendants erroneously claim that Plaintiffs have taken Dr. Woods's admission out of context. It is an odd assertion, given that Plaintiffs laid out his testimony verbatim in their original memorandum. But to avoid any confusion, here is the full questioning leading up to the answer previously cited:

Q. You're not an expert on warnings?

A. Actually, I've been consulted on – I've served on ACOG's Committee on Professional Liability; I was vice chair of that committee. I've also served on the ACOG's Quality and Patient Safety Committee and I'm presently on AUGS' Quality Committee.

Q. Okay. What do those institutions – what do you do with warnings with those three groups?

A. Actually looking on the safety design for, say obstetrical units and these kind of things.

Q. Okay. What do you mean safety design? For the actual unit at the hospital?

A. Yes.

Q. Okay. So you work with warnings for, like, beds in hallways?

A. Well, what I do is looking at hospital design or team design for patient safety, is a better way to describe it.

Q. You're not an expert on warnings related to medical devices, correct?

A. No, I would not call myself an expert.[7]

Somehow, Defendants get from that testimony the claim that Dr. Woods's testimony had something to do with the regulatory process. (Def. Resp. at 9). He said no such thing. He admitted a lack of expertise in warnings with regard to medical devices, period. Defendants also note that this Court allowed testimony about polypropylene from Dr. Johnson, who did not claim to be a biomaterials expert. *See Huskey v. Ethicon, Inc.*, 29 F. Supp. 3d 691, 734 (S.D. W. Va. 2014). However, Dr. Johnson did not expressly deny expertise. *Id.* Regardless, this Court has on several occasions stated that one does not have to be a biomaterials expert to opine about the properties of polypropylene. *See, e.g., Wilkerson v. Boston Scientific Corp.*, No. 2:13-cv-04505, 2015 WL 2087048, at *5 (S.D. W. Va. May 5, 2015) ("Dr. Rosenzweig's established background and skill in pelvic surgery, polypropylene, and the complications associated with degradation qualify him to opine on the degradation process, even though his knowledge about the precise biochemical interactions involved might not be as extensive as that of others.").

This Court has not, however, stated that one does not have to be an expert on warning to opine about warnings. *See In re C.R. Bard, Inc.*, 948 F. Supp. 2d 589, 611 (S.D.W. Va. 2013) (excluding Dr. Shull due to lack of expertise in warnings). This Court should prohibit Dr. Woods from opining about warnings due to his admitted lack of expertise in that area.

This Court should also exclude Dr. Woods's warnings opinions because they are wholly unsupported. As Defendants point out, Plaintiffs have not claimed that Dr. Woods is basing his opinion on matching the complications in his practice to those in the warnings—an opinion that this Court has disallowed. (*See* Def. Resp. at 11). Plaintiffs did not make this argument because it is entirely unclear what the basis is for Dr. Woods's warnings opinions.

[7] *Id.* at 92:19-93:14.

His entire warnings opinion consists of three paragraphs, none of which cites to a single document.[8] The first paragraph simply says that the warnings are adequate. The second paragraph says that he has talked to various people about mesh devices, that increased warnings in 2015 do not mean that the prior warnings were inadequate, and that he is prepared to testify that the warnings are adequate. The last paragraph claims—again, without citation—that the FDA found that full-length slings are safe and effective.[9]

Dr. Woods's warning opinion does not even mention a single warning that appeared on the TVT or TVT-O device at any time.[10] The opinion provides no analysis of anything related to warnings, and no explanation as to what went into the conclusion that the warnings for the TVT and TVT-O were supposedly adequate. Dr. Woods does not even go so far as to say that the warnings given match his clinical experience.[11] Thus, his opinion has less information than the opinion the Court has held to be inadequate. (*See* Def. Resp. at 11).

Given that Dr. Woods admits that he is not a warnings expert and fails to explain how he reached any conclusions about the warnings on the TVT or the TVT-O, this Court should exclude him from giving any testimony in support of the warnings in Defendants' devices.

CONCLUSION

For the reasons stated above, and the reasons stated in Plaintiffs' initial memorandum, the Court should preclude Dr. Woods from giving any opinions about product design or product warnings. Because all of his opinions related to those two areas, he should be excluded entirely from testifying.

[8] Woods Report, Exhibit C to Plaintiff's Motion, at 84-85.
[9] *Id.* at 84-85.
[10] *See id.*
[11] *See id.*

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Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that I filed the foregoing document on May 16, 2016, using the Court's CM-ECF filing system, thereby sending notice of the filing to all counsel of record in this matter.

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